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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,446	03/04/2002	Clara L. Garcia-Rodenas	112843-027	4113

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EXAMINER
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WINSTON, RANDALL O.

ART UNIT	PAPER NUMBER
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1654

12

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/936,446

Applicant(s)  
Garcia-Rodenas et al.

Examiner  
Randall Winston

Art Unit  
1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 9-13, 15-19, and 21-24 is/are rejected.
- 7) ☒ Claim(s) 2, 8, 14, and 20 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Acknowledgment is made of receipt and entry of the claims filed on June 16, 2003.

Claims 1-24 are under examination.

The rejections made under 35 U.S.C. 112, first paragraph, set forth in the previous office action have been overcome by Applicant's amendment.

The rejection made under 35 U.S.C. 112, second paragraph, set forth in the previous office action has been overcome by Applicant's amendment.

The rejection made under 35 U.S.C. 103(a) set forth in the previous office action has been overcome by Applicant's amendment.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7, 10, 13, 16, 19 and 22 as amended are rejected under 35 U.S.C. 102(b) as being anticipated by Dewille et al. (US 5,514, 655).

In Paper No. 11, applicant respectfully request that the obviousness rejection be withdrawn because applicants believe that Nichols fails to disclose or suggest the claimed

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invention. Based on applicant's argument in Paper No. 11, the 103(a) rejection has been respectfully overcome by applicant.

Based on applicant's amendment in Paper No. 14 of claims 1, 7, 13, and 19 (i.e., claims amended to state--from a dietary protein hydrolysate including to a dietary protein hydrolysate in the form of --to overcome the 112, second paragraph, rejection in paper No. 10), applicant claims a nutritional enteral composition and/or method of making and/or of use comprising a mixture of dietary protein hydrolysate having a degree of hydrolysis in a particular range (i.e 10% to less than 50%) by weight, the dietary protein hydrolysate in the form of a mixture of different size peptides and free amino acids, the free amino acids being present in an amount of up to a particular range and intact proteins comprising and/or at least partially and/or at least partly in the form of bioactive peptides in particular ranges wherein the composition also includes other active ingredients such as carbohydrates, lipids, minerals and vitamins in particular ranges whereas the composition provides nutritions and/or promotes the growth and maturation of non-mature gastrointestinal tracts of young mammals.

Dewille et al. anticipate the claimed invention (see, e.g. abstract, column 4 lines 1-10, and claims) because Dewille et al. teach a liquid enteral nutritional product comprising a soy protein hydrolysate having a degree of hydrolysis of 14% to 17 by weight and intact proteins comprising bioactive peptides (please note: that since applicants claim similar intact proteins as Dewille et al, Dewille et al's. intact proteins of caseins and/or whey proteins would inherently contain bioactive peptides such as TGF-B), whereas a soy protein hydrolysate also would inherently be in

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the form of a mixture of different size peptides and free amino acids and whereas since the soy protein hydrolysate and the claimed invention protein hydrolysate utilize a similar degree and/or range of hydrolysis, the soy protein hydrolysate when hydrolysis would inherently contain a similar amount of free amino acids as the claimed invention's free amino acid amount.

Furthermore, the liquid enteral nutritional product also includes other active ingredients such as carbohydrates, lipids, minerals and vitamins to provide nutritions and/or promote the growth and maturation of non-mature gastrointestinal tracts of young mammals when administered.

Therefore, the reference anticipates the instant claim above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5-7, 9, 11-13, 15, 17-19 and 21, 23-24 as amended are rejected under 103(a) as being unpatentable over Dewille et al.

The reference is relied upon for the reasons discussed above. Although not expressly taught based upon the overall beneficial teachings provided by Dewille et al., the adjustment of conventional working conditions (e.g., the result-effective adjustment in the amounts of intact proteins, bioactive proteins and/or other active ingredients such as carbohydrates, lipids, minerals

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and vitamin therein), is deemed merely a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art the time the invention was made, especially in the absence of evidence to the contrary.

### ***Specification***

Claim 2, 8, 14 and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

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CHRISTOPHER R. TATE  
PRIMARY EXAMINER